ISRCTN55086560 https://doi.org/10.1186/ISRCTN55086560

Efficacy and safety of praziquantel, tribendimidine and mebendazole in patients infected with Clonorchis sinensis

Submission date	Recruitment status	[X] Prospectively registered
03/05/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/12/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy and safety of praziquantel, tribendimidine and mebendazole in patients infected with Clonorchis sinensis: a single-centre, open-label, randomised controlled study

Study objectives
Clonorchiasis is one of important food-borne trematodiases which is highly prevalent in east and southeast Asia, especially in China, Korea, northern parts of Vietnam, and the far eastern part of Russia. Chemotherapy is the mainstay for the control of food-borne trematodiasis. Currently, praziquantel is the drug of choice for clonorchiasis. According to the recommendation from World Health Organisation (WHO), the appropriate treatment schedule is 25 mg/kg thrice daily for up to 2 days which results in cure rates of 94100% . Promotion of this dose schedule of praziquantel in mass treatment of clonorchiasis may have certain difficulty, while administration of single dose or reduction of treatment course results in less or unstable efficacy. Therefore, it still needs to develop the new drugs against C. sinensis. In recent years, we found that oral administration of single-dose tribendimidine and mebendazole and multiple-dose albendazole are efficacious. Tribendimidine exhibits not only potential effect against C. sinensis but also potential effect against juvenile C. sinensis. Albendazole was reported to be effective against C. sinensis in rats, and similar results were also shown in experimentally infected dogs. Up to 2005, an experimental study indicated that albendazole and mebendazole showed a potential effect against adult C. sinensis in rats and their single complete curative dose was 150 mg/kg. We aim to assess the efficacy and safety of tribendimidine, mebendazole and albendazole compared with that of praziquantel in patients with parasitologically confirmed Clonorchis sinensis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Committee of the National Institute of Parasitic Diseases, China CDC, 29/04 /2011, no. 2011042901

Study design
Single-centre open-label randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Clonorchiasis

Interventions
Current interventions as of 14/08/2012:
The intervention consists of four treatments, all the medicine is administered orally to each person
1. Multiple-dose praziquantel serves as control, and the total dose is 75 mg/kg (18.75mg/kg twice daily for two days consecutively).
2. Single-dose tribendimidine 400mg.
3. Two doses, on the same day, of Tribendimidine 200mg. The total dose is 400 mg.
4. Single-dose mebendazole 400mg.
All the participants are supervised after treatments, and are asked to report any potential drug related symptoms at 3h and 24h after each time of taking medicine.

Previous interventions until 14/08/2012:
The intervention consists of four treatments, all the medicine is administered orally to each person

1. Multiple-dose praziquantel servers as control, and the total dose is 75 mg/kg(18.75mg/kg twice daily for 2 days consecutively)
2. Single-dose tribendimidine(400mg)
3. Multiple-dose mebendazole, and the total dose is 1500mg (500mg once daily for 3 days consecutively)
4. Multiple-dose albendazole, the total dose is 3200mg(400mg twice daily for 4 consecutive days).
All the participants are supervised after treatments, and are asked to report any potential drug related symptoms at 24h, 48h, 72h, 96h, 120h and 144h after the first dose

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Praziquantel, tribendimidine, mebendazole, albendazole

Primary outcome measure
1. Egg reduction rate (ERR) and cure rate (CR), measured using the Kato-Katz stool examination method
2. Adverse reactions, measured using a standardised questionnaire. The intensity of adverse events was graded as mild, moderate, severe and serious

Assessed at 4 weeks after treatment

Secondary outcome measures
All the participants who are to receive the tribendimidine treatment will accept checks of blood, urine, electrocardiogram, liver function and kidney function before and after the treatment. The abnormal indexes will be supervised and recorded.

Overall study start date
25/06/2012

Completion date
15/08/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/08/2012:
Eligible patients are residents of Hunan province aged 15 to 65 years who have Clonorchis sinensis infections, both sexes.

Previous inclusion criteria until 14/08/2012:
Eligible patients are residents of Guangdong province aged 2 years and above who had Clonorchis sinensis infections, both sexes

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 participants

Key exclusion criteria
1. Pregnant or lactating women
2. Presence of any abnormal medical condition, such as heart disease, high blood pressure, severe malnutrition, severe liver and kidney disease, psychiatric and neurologic disorders
3. Use of praziquantel , tribendimidine, albendazole and mebendazole or any anthelminthic treatment within the past month
4. Enrolled in any other clinical investigation during the study

Date of first enrolment
25/06/2012

Date of final enrolment
15/08/2012

Locations

Countries of recruitment
China

Study participating centre
207 Rui Jin Er Lu
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Sponsor information

Organisation
The National Institute of Parasitic Diseases (China)

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Sponsor type
Government

ROR
https://ror.org/04wktzw65

Funder(s)

Funder type
Government

Funder Name
National Institute of Parasitic Diseases, China CDC (China)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/08/2014		Yes	No